

COMMAND BRIEFING



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WRAIR -SILVER SPRING, MARYLAND



WRAIR MISSION AND VISION

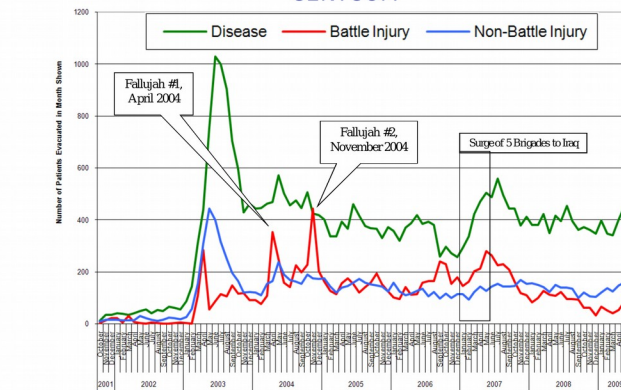
Conduct global medical research to meet DoD requirements and deliver life-saving products to ensure combat effectiveness of the Warfighter.

Become the DoD research organization for the Centers of Excellence in Infectious Disease and Military Psychiatry & Neurosciences.

MILITARY MEDICAL RESEARCH: WHY?

- While battlefield injuries are a predictable outcome of wartime operations, disease and nonbattle injuries remain a major aspect of military healthcare planning
- Focus on the prevention and treatment of militarily-relevant infectious diseases: diarrhea, malaria, leishmania, dengue, etc.
- These same diseases are ones that have limited appeal to the commercial industry owing to business and n

Counts, by Year and Month, of Disease, Non-Battle Injuries, and Combat Injuries Among Service Members Medically Air Transported from CENTCOM



Data Source: USTRANSCOM TRAC/ES

Graph from Armed Forces Health Surveillance Center

As of July 7, 2009



KEY GLOBAL CHALLENGES



“..improve global surveillance and early warning capabilities and quickly enact control and containment measures against the next pandemic threat....

We depend on U.S. overseas laboratories, relationships with host nation governments, and the willingness of states to share health data with nongovernmental and international organizations.”
(p.49)

KEY GLOBAL CHALLENGES: GLOBAL HEALTH



“The United States has a moral and strategic interest in promoting global health....

That is why we are continuing to invest in the fight against HIV/AIDS.....

And we are also pursuing the goal of reducing the burden of malaria and tuberculosis and seeking the elimination of important neglected tropical diseases. ” (p.39)

WRAIR TODAY

1 Major U.S. Labs

3 Major Overseas Locations



~2,000 military/civilian, research/support personnel

WRAIR'S R&D FOCUS

CENTERS OF EXCELLENCE

**Military
Infectious
Disease
Research**

**Military
Psychiatry and
Neuroscience**



CENTER FOR MILITARY INFECTIOUS DISEASE RESEARCH

Worldwide Military Operations Medical Laboratories
Develops/Refines/Validates/Implements/Disseminates
HIV Study Design Research Repository/Surveillance Network



MALARIA

Military Malaria Research Program (MMRP)



- Drugs and Vaccines
- President's Malaria Initiative (PMI)
- Phase III: RTS,S vaccine in children
- IV artesunate
- Surveillance for drug resistant *P. falciparum*
- New antimalarial drugs

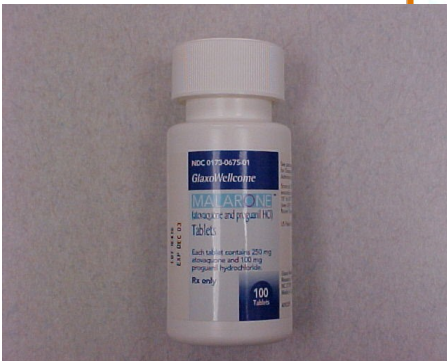
ANTI MALARIAL DRUGS FROM THE DOD

In use

- Chloroquine
- Primaquine
- Chloroquine-Primaquine (*CP tabs*)
- Mefloquine (*Lariam*®)
- Doxycycline (*Vibramycin*®)
- Atovaquone/Proguanil (*Malarone*®)

In later-stage development

- IV Artesunate



HIV



HIV:



33 million cases/year
2.1 million deaths/year

The U.S. Military HIV Research Program (MHRP) —based at WRAIR—aims to:

- § Develop a GLOBALLY effective HIV-1 vaccine
- § Track the HIV epidemic in active-duty forces and assess risk of HIV exposure to U.S. and allied forces deployed overseas
- § Prevention, Care and Treatment

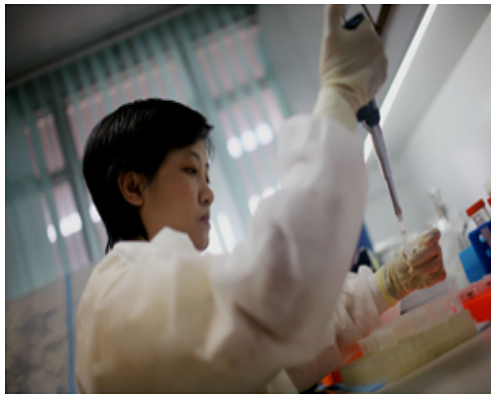
∅ Support the President's Emergency Plan for AIDS Relief (PEPFAR)

Dengue

50-100 million cases/year
25,000 deaths/year

Approaches:

- Multiple vaccine candidates under evaluation
- Long partnerships - field sites with generations of volunteers (Thailand)
- Pediatric clinical trials pending/ongoing in southeast Asia and other endemic areas

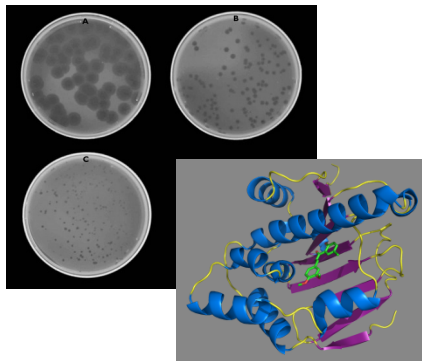


BACTERIAL DISEASES



Diarrheal disease:

- 80-100 million cases/year
- 1.8 million deaths/year
- *Shigella*
- *meningitis*
- Multidrug resistant organisms
- Wound infections



Approaches:

- Vaccines
- Therapeutics
- Diagnostics
- Structural biology

LEISHMANIASIS



1.5-2 million cases/year
80 thousand deaths/year



CAP-accredited diagnostic lab
Device development to detect
latent *Leishmania* sp.
Infection

Experimental therapeutics
Vector/sand fly dipstick assay

VECTOR CONTROL

R&D and testing of products to reduce vector-borne diseases



Sand fly and mosquito studies
Mosquito challenge models

Malaria

Sand flies – Leishmaniasis

Vector control

Repellent development &
testing

Bed nets

Vector Diagnostics
Development

WOUND INFECTIONS



Support Wounded Warrior traumatic injury / infection and the military health care systems

Approach:

Novel therapies

Prevention

Pathophysiology

Diagnostics

Systems biology

Therapeutic intervention

Microbiome technologies applied to
clinical requirements

MEDCOM Multi-Drug Resistant
Repository and Surveillance
Network (P8 funded; \$1.7M per
annum)

CENTER FOR MILITARY PSYCHIATRY AND NEUROSCIENCES

Psychological Resilience



BLAST EFFECTS ON THE BRAIN



Identifying basic injury, mechanisms, modeling and therapy

- Actual blast studies to model the injury
- *In-vitro* & *in-vivo* models
- Kevlar effects - helmets and body armor
- DARPA-funded studies
- Physiology, neuropathology, multi-organ effects
- Experimental therapeutics



ASSESSING PSYCHOLOGICAL RESILIENCE

MENTAL HEALTH ASSESSMENT TEAMS (MHAT), POST DEPLOYMENT HEALTH ASSESSMENT (PDHA)



- **Land Combat Studies I and II:**
 - **Large survey of BCT Soldiers pre and post combat**
- **Annual MHATs:**
 - **Iraq and Afghanistan/changed mental health delivery in theater**
- **In-theater Debriefing:**
 - **Determine whether time-driven debriefings in theater help with Soldier resilience**
- **Emotional Disclosure:**
 - **Determine whether emotional writing (versus factual or no writing) helps with post-combat transition**
- **Neurocognitive Tests after Traumatic Brain Injury**

WRAIR Overseas Laboratories



WRAIR OPERATIONS IN EUROPE

U. S. Army Medical Research Unit Europe (USAMRU-E)

Heidelberg, Germany



Conducts applied psychological research to protect, optimize, and enhance Warfighter psychological resilience.

Examines the psychosocial influences on the causes, cure and prevention of psychiatric battle casualties.

“Human Dimension Research Team” gathers psychological and biomedical data with deployed units to determine the nature and extent of stressors on soldiers

Ascertains the health and performance consequences of stressors

Identifies factors that increase resiliency or vulnerability to stress

WRAIR OPERATIONS IN SOUTHEAST ASIA



Armed Forces Research Institute of the Medical Sciences (USAMC-AFRIMS) Bangkok, Thailand

Conducted bench science, surveillance, and testing of infectious disease medical countermeasures and diagnostics

50-year partnership with the Royal Thai Army conducting infectious disease research

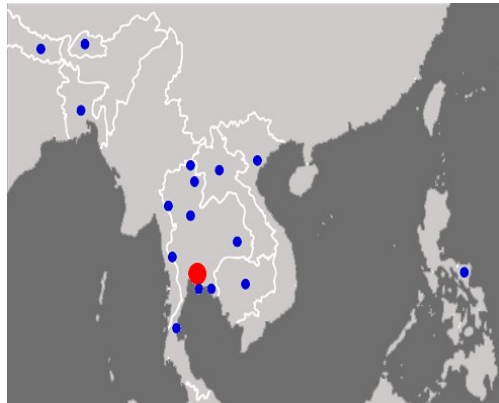
28 Active Duty U.S. Army personnel

350+ local employees

Malaria, dengue, Japanese encephalitis, scrub typhus, HIV, diarrheal diseases, vector control, disease surveillance (GEIS)

AAALAC-accredited animal facility with 600 nonhuman primates

BSL-3 laboratory, CAP certified



● AFRIMS, Bangkok ● Field & Study Sites

WRAR OPERATIONS IN AFRICA



Ondele Research Center, Nyanza Province



U. S. Army Medical Research Unit- Kenya (USAMRU-K)

Nairobi, Kenya

Conducting bench science, surveillance, and testing of infectious disease medical countermeasures and diagnostics

Approx. 40-year partnership with the Kenyan Government conducting infectious disease research

11 Active Duty U.S. Army personnel, 2 GS
> 300 local employees

Malaria, dengue, HIV, diarrheal diseases, vector control, disease surveillance (GEIS), PEPFAR Capabilities in Kenya, Nigeria, Tanzania, and Uganda

R&D effort and PEPFAR

FACILITIES: OUTPATIENT CLINICAL TRIALS

Muriithi-Welde Clinical Research Center,



Modern clinical research center: vaccine/drug studies, storage, etc.

Built with funding from multiple partners: US Army, MVI, USAID, GSK, etc.



PEPFAR

- Ø Functions as an agency and an implementer
- Ø DoD HIV/AIDS Prevention Program (DHAPP), also serving as the PEPFAR Executive Agent for DoD, and the WRAIR/U.S. Military HIV Research Program (USMHRP)
- Ø DHAPP mil-mil: MHRP mil-mil & mil-civ
- Ø Direct DoD PEPFAR funding in focus countries:
 - 50% goes to military programs (many reaching civilian populations)
 - 50% goes to purely civilian programs
- Ø Programs cover the full spectrum of PEPFAR program areas (country dependent)
- Ø DoD provides direct TA to sites via clinical, lab, and prevention experts as well as administration (contracting, fiscal management)

WRAR PREVENTION, CARE AND TREATMENT PROGRAMS VIA U.S. MILITARY HIV RESEARCH PROGRAM

Ø Kenya:

- South Rift Valley: +2.5 million people
- Kombewa District
- Kenya Department of Defence: 100K military + dependents

Ø Nigeria:

- Nigerian Ministry of Defence: 380K active and retired military + dependents and ~1.5 million civilians

Ø Tanzania:

- Southern Highlands: 6 million people
- Tanzania Peoples Defence Forces: 120K military + dependents and ~800K civilians

Ø Uganda:

- Kayunga District: 300K+ people

PROCUREMENT NEEDS & PROCESSES

Ø What we need...

Commercial Goods – Laboratory and administrative materials and supplies, capital equipment , animals and animal supplies

Construction Services – Upgrades

Integrated R&D and Non-personal Research Services

Ø How it's procured...

Commercial Items & Commercial Services

- **Credit Card Orders**
- **Established Contracts**
- **New Contracts**

R&D

- **Contracts (Procurement, SBIR, STTR)**
- **Grants & Cooperative Agreements (BAA)**
- **Cooperative Research and Development Agreements (CRADA)**
- **Commercial Test Agreements (CTA)**
- **Interagency Agreements**

ACQUISITION: TO DATE AND FORECASTED

To Date

Service contracts

Approximately \$41M

Expendable medical

Lab supplies, reagents

Approximately \$1M

Expendable medical/other credit card purchases

Approximately \$10M

Construction - Renovation

Approximately \$15M

Forecasted Acquisition

\$5M (all types)

WRAIR: A UNIQUE NATIONAL ASSET

Leveraging Capacity and Expertise to Serve the Soldier

- Prominent Infectious Disease and Military Behavioral Health and Neurosciences Research Groups
- Only Malaria Drug Discovery/Development Program for the U.S.
- Close Partnerships with the State Dept and NIAID in HIV Research
- Other Partnerships: Gates, MVI, MMV, CDC, USAID, etc.
- Overseas Research Platforms - Europe, Asia, and Africa
- Pilot Bioproduction Facility—a Strategic DoD Asset
- Clinical Trials Centers on 3 Continents
- World-renowned programs in psychiatry, sleep management and neuroscience
- Well modeled and elegant preclinical work in brain injury
- AAALAC- Accredited Animal Facilities (US & Thailand)
- Surveillance network for wound infection pathogens

